

### REMARKS

The Examiner rejected Claims 1-13 under 35 U.S.C. § 102(b) as being anticipated by Sweezer et al. (U.S. Patent No. 5,478,309) ("Sweezer"). The Examiner stated that, "Sweezer discloses a catheter system and method for providing cardiopulmonary bypass pump support during heart surgery that includes a delivery conduit (19) with an occlusion balloon (27), a collection conduit (1) with an occlusion balloon (6), a driving force (33) in communication with the delivery conduit, and an inflation/deflation control mechanism (43). The balloons are contractable. The perfusion fluid includes cardioplegia solution (chemotherapeutic chemicals)." (Examiner's Office Action)

Applicant respectfully submits that Sweezer fails to teach Applicant's claimed invention; the elements required by independent Claims 1 and 14 and dependent Claims 2-13 and 15-22 are not taught by Sweezer.

Sweezer is directed to a device that is used in obtaining total cardiopulmonary bypass support and isolation of the heart during performance of a heart surgery, "The present invention is directed to a catheter system and method for achieving total cardiopulmonary bypass of the heart during heart surgery with provisions for proximal aortic occlusion, aortic root cardioplegia delivery, aortic root venting, and left ventricular decompression. The system comprises a cardiopulmonary bypass pump which has an inlet port for reception of oxygen depleted blood from the venous circulation, and an outlet port for the delivery of oxygen-rich blood to the arterial circulation." (Sweezer, col. 5, lines 47-56.)

Sweezer can also be used to deliver a cardioplegia solution to the heart, "To deliver cardioplegia solution, a first proximate port on the cannula communicates with

the first lumen and the cannula contains an orifice adjacent its distal end which is in communication with the first lumen thereby defining a single flow path for either the passage of cardioplegia solution or for the evacuation of fluid from the aortic root.” (Sweezer, col. 5, lines 62-28.)

Sweezer allows for the selection of either the flow of cardioplegia solution or evacuating fluid from the aortic root through the single flow path.

Sweezer discloses a number of embodiments of how a cardioplegia solution may be perfused into the aortic root. One example is shown in Figs. 15-19, “Each of the arterial perfusion catheters described in Figs. 15 through 19 embody an extended distal portion which may be extended across the aortic valve and into the left ventricle to provide a left ventricle venting function; cardioplegia solution may still be delivered into the aortic root as in the above-described embodiments of the arterial perfusion catheter or the same flow path may be used for aspiration of the aortic root.” (Sweezer, col. 17, lines 9-18.)

The cardioplegia solution in this embodiment is introduced through the orifices marked 91” which are located below the balloon catheter labeled as 27 (see Fig. 15).

Sweezer does not disclose a collection means for the cardioplegia solution. Therefore, the solution will be free to flow throughout the cardiopulmonary system.

Sweezer discloses and illustrates another embodiment illustrated in Fig. 21, where the “ ... distal tip 128 has a plurality of orifices 136 for delivering a cardioplegia solution into the coronary artery for arresting the heart.” (Sweezer, col. 20, lines 45-48.)

Sweezer does not disclose a collection means for the cardioplegia solution in this embodiment either. Therefore, the cardioplegia solution will be free to flow into the coronary arteries, the left ventricle and atrium, and the remainder of the cardiopulmonary system.

Another embodiment of the catheter is illustrated in Fig. 27, where, " ... a cardioplegia solution may be injected into the aortic root for flow into the coronary arteries to arrest the heart ... the multiplicity of venting orifices 191 located adjacent to inflatable balloon 127' permit either the infusion of the cardioplegia solution or venting of the aortic root." (Sweezer, col. 22, lines 16-23.) Again, Sweezer does not disclose a collection means to keep the cardioplegia solution from flowing throughout the rest of the cardiopulmonary system.

Sweezer illustrates another embodiment in Fig. 38 where arterial venting orifices 291 are utilized for the injection of the cardioplegia solution into the aortic root. (This embodiment is also illustrated in Fig. 39.) Again, Sweezer does not disclose a means to collect the cardioplegia solution to prevent it from flowing into the rest of the cardiopulmonary system.

Sweezer does disclose a number of embodiments of a collection catheter. However, this catheter is not used for the collection of the cardioplegia solution that is used to stop the heart, but the collection catheter is used to collect de-oxygenated blood from the venous system. That collected blood is then fed through a cardiopulmonary bypass system where it is oxygenated and re-inserted as oxygenated blood in the aorta to bypass and isolate the heart for surgical procedures.

Applicant respectfully submits that Sweezer does not disclose the requirements of Applicant's Claim 1, including, " ... a collection conduit for acquiring the fluid, the collection conduit positioned adjacent to or into one of the downstream channels and having a collection seal for occluding external fluid flow." Sweezer does provide for a delivery conduit for delivering a cardioplegia solution to the heart, but does not disclose a collection conduit for collecting the cardioplegia solution.

Applicant respectfully requests that the Examiner withdraw the rejection to Claims 1-13 under 35 U.S.C. § 102(b).

Attached hereto is a marked-up version of the change made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

**CONCLUSION**

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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Dated: 5/10/02

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**CERTIFICATE OF MAILING:**

I hereby certify that this correspondence is being deposited as First Class Mail with the United States Postal Service in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on May 10, 2002.

Nadya Gordon 5/10/02  
Nadya Gordon Date

Attachment: VERSION WITH MARKINGS TO SHOW CHANGES MADE

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

1. (Amended) A system for fluid isolation in a biological mass having at least one upstream channel and at least one downstream channel, comprising:

a delivery conduit for administering a fluid to the biological mass, the delivery conduit positioned adjacent to or into one of the upstream channels; and

a collection conduit for acquiring the administered fluid, the collection conduit positioned adjacent to or into one of the downstream channels and having a collection seal for occluding external fluid flow.